

Patent US 201C4 Attorney Docket No. 892,280-155

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Group Art Unit: 1614

CAVALERI et al.

Serial No. 10/828,439

Filed: April 16, 2004

For: STABLE PHARMACEUTICAL

COMPOSITIONS OF

DALBAVANCIN AND METHODS

OF ADMINISTRATION

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97–1.98, information relating to the above–identified application is hereby disclosed. The accompanying Form PTO–1449 provides a listing of documents that may be relevant to the subject application.

It is requested that the Examiner fully consider the art cited in the accompanying Form 1449, initial the left-most column of the form adjacent each cited reference, and return a copy

CERTIFICATE OF MAILING (37 C.F.R. §1.8a)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as First Class Mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.

Date of Deposit IR1:1058723.1 Cynthia B. Pacheco

for Applicants' records. It is further requested that the art be cited on the cover of any patent issuing from the subject application.

This IDS is believed to be timely in that it is being submitted under 37 CFR § 1.97(b), that is (1) within three months of the filing date of the application, which is not a continued prosecution application filed under § 1.53(d); or (2) within three months of entry of the national stage as set forth in 37 CFR § 1.491; or (3) before the mailing of a first Office action on the merits; or (4) before the mailing of a first Office action after filing a request for continued examination under § 1.114. Thus, no fee is required.

Applicants' would like to bring to the Examiner's attention that the four references included in the attached International Search Report and Form 1449 were previously cited in the Information Disclosure Statement filed on April 16, 2004 on Sheet 1, No. 14, Sheet 8, No. 118, Sheet 10, No. 154, and Sheet 3, No. 59. In accordance with §1.98(d), copies of the references listed on the attached Form PTO–1449 are not enclosed herewith because they were previously cited by or submitted to the Patent and Trademark Office in one or more of the prior U.S. Application Serial No. 10/714,261, filed November 14, 2003, which claims the benefit of U.S. Provisional Patent Application Serial Nos. 60/427,654, filed November 18, 2002, 60/485,694, filed July 8, 2003, 60/495,048, filed August 13, 2003, and 60/496,483, filed August 19, 2003, by CAVALERI, et al. for which a claim for priority under 35 U.S.C. §120 has been made in the instant application. Accordingly, Applicants will provide duplicate copies in respect of the present case only if the Examiner so desires.

This statement should not be construed as a representation that more material information does not exist or that an exhaustive search of the relevant art has been made. Nor

Attorney Docket No. 892,280-155

does this statement constitute an admission by Applicants or Applicants' agent that the information provided herein is necessarily prior art to Applicants' invention. Moreover, Applicants reserve the right to establish the patentability of the claimed invention over any of the listed documents should they be applied there—against as references.

Respectfully submitted,

O'MELVENY & MYERS LLP

Dated: 10/7/04

By

Diane K. Wong

Attorneys for Applicant

DKW/kmg O'Melveny & Myers LLP 114 Pacifica, Suite 100 Irvine, CA 92618-3315 (949) 737-2900

PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are require respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

Sheet 1

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

of 2

Complete if Known		
Application Number	10/828,439	
Filing Date	April 16, 2004	
First Named Inventor	Cavaleri	
Art Unit	1614	
Examiner Name	Not yet assigned	
Attorney Docket Number	892 280-155	

			U. S. PATEN	T DOCUMENTS	
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ^{2 (f known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	^{US-} 5,750,509	05-12-1998	Malabarba	
	<u> </u>	US-	00 12 1000		
		US-			
		US-	 		
		US-			
	<u> </u>	US-			
	1	US-			
		US-			
	-	US-			,
8		US-			
		US-			

FOREIGN PATENT DOCUMENTS						
Examiner Cite Initials* No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages		
		Country Code ^{3 -} Number ^{4 -} Kind Code ⁵ (if known)	MM-DD-YYYY		Or Relevant Figures Appear	T ⁶

Examiner	Date	-
Signature	Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08B (08-03)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO		Complete if Known			
Cubsina	10 10 10 11 1445/1 TO			Application Number	10/828,439
INF	ORMATION	DIS	CLOSURE	Filing Date	April 16, 2004
STA	STATEMENT BY APPLICANT		First Named Inventor	Cavaleri	
	(Use as many she	oto oo n	00000000	Art Unit	1614
	(USE as many sne	ets as n	ecessary)	Examiner Name	Not yet assigned
Sheet	2	of	2	Attorney Docket Number	892,280-155

,		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	C1	A. MALABARBA et al, "Glycopeptide derivatives", Current Medicinal Chemistry, Vol. 8, 2001, pp. 1759-1773	
	C2	T. STAROSKE et al, "Synthesis of covalent head-to-tail dimers of vancomycin", Tetrahedron Letters, Vol. 39, 1998, pp. 4917-4920	
	C3	G. CANDIANI et al., "In-vitro and in-vivo antibacterial activity of BI 397, a new semi-synthetic glycopeptide antibiotic", Journal of Antimicrobial Chemotherapy, Vol. 44, 1999	
	<u></u>		

Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.